DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 9, 2015

Medicrea® International S.A.
Mr. David Ryan
Marketing and Product Development Director
14 Porte du Grand Lyon
Neyron 01700
France

Re: K141398
Trade/Device Name: PASS LP Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP
Dated: December 5, 2014
Received: December 8, 2014

Dear Mr. Ryan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141398

Device Name
PASS LP SPINAL SYSTEM

Indications for Use *(Describe)*
The PASS LP Spinal System is a pedicle screw fixation system intended for immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (e.g., fracture or dislocation), deformity or curvature (e.g., scoliosis, kyphosis, and/or lordosis), tumor, spinal stenosis, pseudoarthrosis, or failed previous fusion.

Except for rod plates, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the PASS LP Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the system is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis and fracture caused by tumor and/or trauma. The PASS LP Spinal System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

MEDICREA INTERNATIONAL S.A.'s PASS LP – Additional Components

1. DEVICE SUBMITTER

MEDICREA® INTERNATIONAL S.A.

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Marketing and Product Development Director
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Date Prepared: 12/05/2014

2. DEVICE

Name of Device: PASS LP Spinal System

Common or Usual Name: Spinal Lumbar Fixation System

Classification Name: Pedicle Screw Spinal System

- ✓ orthosis, spinal pedicle fixation per MNI 888.3070
- ✓ orthosis, spondylolisthesis spinal fixation per MNH 888.3070
- ✓ appliance, fixation, spinal interlaminal per KWP 888.3050
- ✓ pedicle screw spinal system, Adolescent Idiopathic Scoliosis per OSH 888.3070
- ✓ orthosis, spinal pedicle fixation, For Degenerative Disc Disease per NKB 888.3070

Regulatory Class: III

Product Code: NKB, OSH, MNI, MNH, KWP

3. PREDICATE DEVICES

CD Horizon Spinal System (MEDTRONIC, K140449) [Primary Predicate]

PASS LP Spinal System (MEDICREA INTERNATIONAL, K123138)

4. DEVICE DESCRIPTION

The PASS LP Spinal System is designed to contribute to correction and surgical stabilization of the thoracic, lumbar and sacral spine.

The system consists of pedicle screws, hooks, sacral plates, iliac screws, clamps, rods, nuts, rod plates and crosslink components. It can be used for single or multiple level fixations. Components are manufactured from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136 or cobalt-chromium molybdenum alloy Co-Cr28Mo6 that conforms to ISO 5832-12 and ASTM F1537.

The purpose of this submission is to add components to the PASS LP implant range to treat Pars interarticularis fracture.

A subset of PASS LP Spinal System components may be used for posterior pedicle screw fixation in pediatrics cases. These constructs may be comprised of a variety of shapes and sizes of rods, hooks, sacral hooks, sacral plates, iliac screws, clamps, nuts and crosslink components. These components can be rigidly locked into a variety of configurations.

5. INDICATIONS FOR USE

The PASS LP Spinal System is a pedicle screw fixation system intended for immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (e.g., fracture or dislocation), deformity or curvature (e.g., scoliosis, kyphosis, and/or lordosis), tumor, spinal stenosis, pseudoarthrosis, or failed previous fusion.

Except for rod plates, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the PASS LP Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the system is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis and fracture caused by tumor and/or trauma. The PASS LP Spinal System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The table below compares the features and characteristics of MEDICREA® INTERNATIONAL S.A. PASS LP Spinal System – Additional components to their predicate devices.

Device	**PASS LP – Additional components**	**CD Horizon Spinal System (MEDTRONIC)**	**PASS LP Spinal System (MEDICREA INTERNATIONAL)**	**PASS LP Spinal System (MEDICREA INTERNATIONAL)**
510(k) number	K141398	K140449	K123138	K123138
Intended use				
Thoracic	Yes	Yes	Yes	Yes
Lumbar	Yes	Yes	Yes	Yes
Posterior Approach	Yes	Yes	Yes	Yes
Design				
Rod Diameters	Ø4mm	Ø3,5mm to Ø6,35mm	Ø5.5 and Ø6 mm	Ø5.5 and Ø6 mm
Hooks	Yes One size available Left and Right version	Yes Several Options	Yes Several Options	Yes Several Options
Crosslink	Yes	Yes	Yes	Yes
Materials				
	Ti-6Al-4V (ASTM F136 & ISO 5832-3)	Titanium Alloy or Stainless Steel	Ti-6Al-4V (ASTM F136 & ISO 5832-3) Or Co-Cr 28Mo6 alloy 1 (following the ASTMF1537 and ISO 5832-	Ti-6Al-4V (ASTM F136 & ISO 5832-3) Or Co-Cr 28Mo6 alloy 1 (following the ASTMF1537 and ISO 5832-

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

To determine substantial equivalence of the PASS LP components to its predicate, Dynamic Compression Bending Tests, following the ASTM F1717 *"Standard Test Methods for Spinal Implants Constructs in a Vertebrectomy Model"* were carried out. Those tests demonstrated substantially equivalent performance of the components to its predicate.

8. CONCLUSION

MEDICREA® INTERNATIONAL S.A. PASS LP Spinal System – additional components are substantially equivalent to the already cleared PASS LP components (MEDICREA INTERNATIONAL, K123138) and the CD Horizon Spinal System (MEDTRONIC, K140449) in terms of intended use, materials used, sterilization, mechanical safety and performances.